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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,734	10/06/2000	Ib Mendel-Hartvig	10806-129	1611

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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	17

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,734	Applicant(s) MENDEL-HARTVIG ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 6 "Reactant* " is vague and indefinite. It is unclear what "*" represents. Does it represent a label or marker, or does it represent some other biospecific affinity reactant? See deficiencies throughout the claims.

Claim 1, line 6, "firmly anchored" is vague. It is unclear what is considered to be firmly anchored. Does it mean that the reactant never comes off or does it mean that

the bond has a strength that will allow for the reactant to withstand a certain amount of force? See deficiencies throughout the claims.

Claim 1, line 7, "Reactant I" is vague. It is unclear what "I" represents. See deficiencies throughout the claims.

Claim 1, line 7 "one is firmly anchored in the matrix" is vague and indefinite. It is unclear what is anchored, the analytically detectable reactant or some other reactant?

Claim 1, part (A) the recitation "the reactants" is vague. Is it referring to the biospecific affinity reactants or the analytically detectable reactant (Reactant*)?

Claim 1, part (B) the recitation "with the firmly anchored reactant" is vague. Does this mean that the firmly anchored reactant is anchored within the detection zone or does it mean that there is a firmly anchored reactant located downstream of the application zone for liquid?

Claim 1, line 25 the recitation "being related to" is vague. It is unclear what relationship applicant is referring to.

Claim 1, line 29 the recitation "substantially" is vague. It is unclear what is considered to be substantial. See deficiencies throughout the claims.

Claim 1, line 33, the "arrow" is a relative symbol which renders the claim indefinite. It does not indicate the direction because the direction is relative to the positioning of the paper. See also deficiency found in part (d). See also deficiencies found in claim 20.

Claim 1, part (c) "n'' " and "n' " is vague and indefinite. It is unclear what the recitations represent and also what they are referring to. See also deficiency found in

claim 20. Also " n">= n' " is vague. Does this mean that the application zone for the Reactant* appears before the application zone for sample? See deficiencies throughout the claims.

Claim 1, part (c) the recitation "one LZn" is vague. Is it the same as LZ1 or does it mean that the application zone is different for both the sample and the Reactant*? See also deficiency found in claim 20.

Claim 5, line 2 "LZn+1" is vague. It is unclear what applicant intends. Does this mean one more application zone is added and if so in what location. See deficiencies throughout the claims. See also the deficiency throughout the claims of the recitation "LZn-1 or –2).

Claim 8, line 4 "as far as allowed by" is vague. It is unclear what applicant intends.

Claim 11, "the composition" there is insufficient antecedent basis for this limitation.

Claim 12, line 3 "....." is vague. It is unclear what applicant intends and it is also unclear what these "....'s" represent.

Claim 14, line 3 "Reactant' " is vague. It is unclear what " ' " represents.

Claim 14, line 4, the recitation complex "Reactant' " is vague. It is unclear if Reactant' is actually complexed to something before forming the complex with analyte-Reactant* or if it is a single biospecific reactant that is complexed to the analyte-Reactant* complex.

Claim 17, the recitation "generally" is a relative term which renders the claim indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-14, 18-28, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dafforn et al (US Patent 4,981,786).

Dafforn et al disclose an immunoassay device and method for determining an analyte in a sample. Dafforn et al also disclose that the device comprises a bibulous material which is susceptible to traversal by an aqueous medium in response to capillary force (flow matrix), (col 7, lines 8-10). Dafforn et al disclose that the device may be used in assays wherein absorbent material is utilized to assist the flow of liquid away from a contact portion where the absorbent material is contacted with a medium containing the analyte to be determined or reagents for analyzing for the analyte (col 4, lines10-16). Dafforn et al disclose the device comprises a first means for introducing a sample into the device and second means other than the first means for introducing a liquid reagent other than the sample into the device (col 3, lines1-20). Dafforn et al disclose that the liquid reagent (Reactant*) is added upstream of the test solution (sample) and that both of these application zones are located upstream of a

immunosorbing zone (detection zone) (see also figure 10) and that specific binding members (antibodies) are immobilized in the immunosorbing zone (col 18, line 3 – col 19, line 48). Dafforn et al also disclose that the sample may be introduced before the liquid reagent if so desired (col 18, lines 20-32). Dafforn et al that the contact portion can also serve as the immunsorbing zone (detection zone) or separate immunosorbing zones can be utilized depending on the particular assay protocol chosen (col 18, lines 45-48). Dafforn et al also disclose that the application of liquid can be performed simultaneously in the application zones (col 24, lines 30-32). Dafforn et al also disclose that the reagents can be predeposited in the matrix. Dafforn et al also disclose packaging the components into a kit.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 15, 16, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dafforn et al in view of Robinson et al (WO 95/16914).

See above for teachings of Dafforn et al.

Dafforn et al differ from the instant invention in failing to disclose the matrix comprising at least one calibrator zone, in which calibrator is bound.

Robinson et al disclose the use of calibration zone(s), in which a calibration reagent is immobilized and has biospecific affinity for the analyte of interest or the

binding partner of interest (page 15, lines 15-24). Robinson et al also disclose that the device may be a flow through device such as a lateral flow matrix (page 5, lines 7-22).

Robinson et al also disclose that the specific binding partner can be coupled to or conjugated to the calibrator (see page 17), to form a complex for detection. Robinson et al disclose that the reagents may be antigen/antibody complexes. Robinson et al disclose that calibrator zones used in this manner offers means for calibrating the assay as part of the assay procedure (page 3, lines 15-16) and also provides advantages for additional compensation for various factors in the assay system which may influence the level of signal observed (page 14, lines 24-26).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a calibrator zone as taught by Robinson et al into the method and device of Dafforn et al because Robinson et al disclose that calibrator zones used in this manner offers means for calibrating the assay as part of the assay procedure (page 3, lines 15-16) and also provides advantages for additional compensation for various factors in the assay system which may influence the level of signal observed (page 14, lines 24-26).

9. Claims 17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dafforn et al (US Patent 4,981,786) in view of Self et al (US Patent 4,446,231).

See above for teachings of Dafforn et al.

Dafforn et al and differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et al shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al shows that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances. Therefore it would have been obvious to one of ordinary skill in the art to use the device and method of Dafforn et al for diagnosing autoimmune disease.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ullman et al (US Patent 4,857,453) disclose a device having at least two application zones in which the liquid reagent zone is located upstream of the sample application zone and the detection zone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
April 2, 2002

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SUPERVISORY PATENT EXAMINER
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04/05/02